INSTITUTE: National Eye Institute

STUDY NUMBER: 03-EI-0122

PRINCIPAL INVESTIGATOR: Robert B. Nussenblatt, M.D.

STUDY TITLE: Evaluation of Immune Responses to Different Antigens in Non-Infectious Ocular Inflammatory Diseases

Continuing Review Approved by the IRB on 08/04/15
Amendment Approved by the IRB on 07/24/14 (G)
Date Posted to Web: 08/05/15
Standard

INTRODUCTION

We invite you (your child) to take part in a research study at the National Institutes of Health (NIH).

We want you (your child) to know that:

Taking part in an NIH research is entirely voluntary.

You (your child) may choose not to take part, or you (your child) may withdraw from the study at any time. In either case, you (your child) will have the standard of care to which you (your child) are otherwise entitled. However, to receive care at the NIH, you (your child) must be taking part in a study or be under evaluation for study participation.

You (your child) may receive no direct benefit from taking part in this study.

Before you (your child) decide to take part in this study, please take as much time as you (your child) need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your (your child's) personal physician or other health professional.

Purpose

The purpose of this study is to better understand your (your child's) eye disease.

Background

Ocular inflammatory diseases, Age related macular degeneration (AMD) and diabetic retinopathy can lead to visual loss in adults as well as in children. It is possible that the immune system reacts against normal components of the eye and may cause some of the eye damage in these diseases. We can study the activity of the immune system but testing immune cells and immune reactions in your (your child's) blood. We hope that this study will help improve our understanding of your (your child's) eye disease and may help us develop better treatments in the future.

Study Population

Up to 400 participants with Ocular inflammatory diseases, Age related macular degeneration (AMD) or diabetic retinopathy will participate in this study.

Who Can Be In This Study

You (your child) may be eligible for this study if you (your child):

1. Are (Is) 6 years old or older and have an ocular inflammatory disease, Age related macular degeneration (AMD) or diabetic retinopathy, based on examination in the NEI eye clinic during participation in another NEI protocol.

Who May Not Be In This Study

You (your child) may not be eligible for this study if you (your child):

1. Are (Is) unable or unwilling to give a blood sample.

Procedures

We will take your (your child's) medical and eye disease history and review the information on your (your child's) previous eye examinations at NEI in your (your child's) medical record from your (your child's) participation in other NEI protocols.

If our review confirms that you (your child) qualify for participation, we will draw blood from a vein in your (your child's) arm.

You (your child) are being followed by your (your child's) doctors for an ocular condition and they have determined that you (your child) may be eligible for this study. You will give a blood sample for this study.

Blood Drawing. Blood will be drawn through a needle in your arm. We will draw no more than 100 mL (less than ½ cup) of blood from adults per visit. No more than 10.5 mL/kg or 550 mL (2 1/3 cups) of blood, whichever is less, will be drawn from adults over any eight-week period. For children, no more than 5 mL/kg or 100 mL (less than ½ cup) of blood, whichever is less, may be drawn per visit. No more than 9.5 mL/kg may be drawn over any eight-week period.

These samples will be used for the study described in this consent form and all samples will be discarded upon completion of the study analysis**.**

Risks, Inconveniences and Discomforts

Risks of Blood Drawing. You may experience some discomfort at the site of needle entry, and there is a risk of bruising. There is a remote risk of fainting or local infection.

Benefits

There is no direct benefit to you from participating in this research study, however, we hope to learn more about eye inflammatory diseases that may help you or others in the future.

Right of Withdrawal

You may withdraw from the study at any time and for any reason without loss of benefits or privileges to which you are otherwise entitled. The investigator can remove you from the study at any time if she or he believes that continuation is not in your (your child's) best medical interest or if you are unable to comply with the requirements of the study. If you withdraw from the study, any portion of your (your child's) samples not already analyzed will be destroyed and your (your child's) information will be deleted from the database that is associated with this study. If you decide to withdraw from the study, please contact Patti Sherry, RN, BSN, CCRP at 301-435-4529.

Results From this Study

The information we obtain from this study will not provide information on your (your child's) health. You will not receive any individual results.

Alternatives to Participation

The alternative to participating in this study is not to participate. This study does not provide treatment and does not replace any therapy that your (your child's) own doctor is giving you.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your (your child's) rights as a research participant, or about any research-related injury, contact the Principal Investigator, Dr. Robert B Nussenblatt, MD at Building 10, Room 10S219, Telephone: 301-496-3123.

You may also call the Clinical Center Patient Representative at 301-496-2626.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/Legal Representative _____ Date _____

Print Name _____

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/Guardian _____ Date _____

Print Name _____

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian _____ Date _____ Print Name _____

THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM AUGUST 04, 2015 THROUGH AUGUST 3, 2016.

Signature of Investigator _____ Date _____

Print Name _____

Signature of Witness _____ Date _____

Print Name _____